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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,649

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Eric Abel

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25006

7590

11/09/2009

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EXAMINER

GRAHAM, BRIAN J

ART UNIT

PAPER NUMBER

3734

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,649	<b>Applicant(s)</b> ABEL ET AL.	
	<b>Examiner</b> BRIAN GRAHAM	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 18, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "the stressed position" in line 3, and it is unclear whether this refers to the collapse position of the expansion position, as both as recited as being stressed positions previously in the claim.

The term "minimised" in claim 18 is a relative term which renders the claim indefinite. The term "minimised" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

Claim 25 recites the limitation "the shape memory alloy" in line 3. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 13-17, 20-23, 27, 31-32, and 34-35 are rejected under 35

U.S.C. 102(b) as being anticipated by Shaw *et al.*, hereinafter referenced as “Shaw”

(United States Patent Number 5,678,572).

Shaw discloses a medical apparatus having a leading end (11) and an area for access from the apparatus into a body passage (see Figure 4b, area between 1 and 1'), part of which is spaced from the leading end. The apparatus is controllably movable between a collapse position (Figure 4a) and an expansion position (Figure 4b) by controllably elastically deforming expansion arms (1, 1').

Regarding claim 2, Shaw discloses the stay sleeves having a plurality of holes which allows the stays to be incrementally expanded (col. 2, lines 23-28).

Regarding claim 13, Shaw discloses screws (21, 21') used to lock the device in a desired position.

Regarding claim 14, the access area extends from the leading end and part way along a length of the apparatus (see Figure 4b).

Regarding claims 15-16, Shaw discloses a guide member (11'') which defines the leading end and the access area which is spaced from the leading end.

Regarding claim 17, the access area is definable as an aperture in the wall of the guide member.

Regarding claim 20, the access area extends around the entirety of the device except for the guide member, which is shown to be less than half of the perimeter of the device (Figure 4b).

Regarding claim 21, Shaw discloses an inlet (Figure 2, inlet near ref. 211) at the trailing end to allow access into the apparatus.

Regarding claims 27 and 31, Shaw discloses an embodiment utilizing a soft inflatable tube extending between the leading end and the base of the device which is inflated to move the apparatus to the expansion position (col. 2, lines 57-62). The inflatable tube would be definable as a flexible cover extending between the expansion device and the guide member.

Regarding claim 32, when manually pushing the stay pushers (12), an operator of the device would receive force feedback from the stay pusher.

Regarding claims 34 and 35, Shaw discloses inserting a medical apparatus into a body passage in the collapse position, moving the apparatus into the expansion position by providing an expansion force on the apparatus, controllably elastically deforming expansion arms, and accessing the body passage (col. Col. 1, lines 48-62).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 19, 24, and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw.

Regarding claims 7 and 36, Shaw discloses the claimed invention except for the arms being at rest in the expanded state, versus being at rest in the unexpanded state. It would have been an obvious matter of design choice to make the expanded state the resting position of the arms, since applicant has not disclosed that choosing one state over the other for the resting state solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the resting state being the unexpanded state. Furthermore, if the expanded state were used as a resting state, it would have been obvious to provide a collapse force in the device in order to insert it into a body cavity and then release the collapse force to expand the device inside the body cavity.

Regarding claim 19, Shaw fails to specifically disclose the access area having a greater dimension longitudinally than laterally. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device with an opening that was larger longitudinally than laterally.

Regarding claim 24, Shay discloses the claimed invention except for shape memory alloy material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use shape memory alloy material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claim 37, while Shaw fails to specifically disclose the steps of moving the apparatus from the expansion position to the collapse position and removing the apparatus from the body passage, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include such steps in order to avoid leaving a patient with an expanded device still housed within their body.

Regarding claims 38 and 39, while Shaw fails to disclose rotating and re-expanding the device, with or without removing it from the body passage, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such steps in order to gain access to a desired portion of the patient's body.

Regarding claims 40-41, while Shaw does not specifically disclose viewing the body passage or conducting a diagnostic procedure on the body passage, he does disclose the passage being used for surgical procedures, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to view the passage prior to or during such procedures, and to include diagnostic procedures.

Claims 8-9, 11-12, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Armstrong (United States Patent Application Publication Number 2002/0111639).

While Shaw fails to disclose an actuator mechanism with an activating member, Armstrong discloses an anoscope which utilizes a ratchet mechanism (75) including a slider (74) coupled to the activating member (14) and a locking member (unlabeled) wherein movement of the slider relative to the locking member is adapted to move the

activating member relative to the remainder of the apparatus, thereby moving the apparatus between the collapsed and expanded positions.

Regarding claim 12, it is old and well known to motorize movements that were previously controlled by hand.

Regarding claim 26, the movement of the actuating device (22) of Armstrong would serve to advance the activating member (14) which would cause the distal movement of the stays of Shaw, moving the device from the collapsed to the expanded position.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Nobles *et al.*, hereinafter referenced as "Nobles" (United States Patent Application Publication Number 2002/0013601).

While Shaw fails to disclose a plurality of inflatable elements, Nobles discloses a cavity enlarger apparatus which comprises two annular inflatable chambers (104, 106) spaced axially on either side of a central cylindrical access area (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflatable chambers of Nobles in the device of Shaw in order to provide additional securing means to hold the device in place.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Armstrong, as applied to claim 9 above, and further in view of Flack (United States Patent Number 1,267,066).



Where Shaw and Armstrong fail to disclose a screw mechanism for expanding the dilator, Flack discloses a dilator which uses a screw mechanism to enact expansion (Figures 1 and 2, lines 46-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a threaded expansion mechanism as disclosed by Flack in the modified invention of Shaw and Armstrong in order to provide a more articulate, finely-adjustable expansion mechanism.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Nobles and further in view of Addis (United States Patent Number 6,656,154).

Shaw fails to disclose a device for measuring the expansion force of the expander. However, It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflatable chambers of Nobles in the device of Shaw in order to provide additional securing means to hold the device in place. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pressure-gauge of Addis (which would measure the force of the expansion balloons of Nobles), in the device of Shaw in order to provide a means for measuring the pressure used to expand the rectum, and avoid harming the patient with over-expansion or application of high amounts of force.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-

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7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BJG/

November 2, 2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734